

111TH CONGRESS
2D SESSION

H. R. 1032

IN THE SENATE OF THE UNITED STATES

NOVEMBER 15, 2010

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

To amend the Public Health Service Act to improve the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Heart Disease Edu-
3 cation, Analysis Research, and Treatment for Women
4 Act” or the “HEART for Women Act”.

5 **SEC. 2. REPORT BY GOVERNMENT ACCOUNTABILITY OF-**
6 **FICE.**

7 (a) IN GENERAL.—The Comptroller General of the
8 United States shall conduct a study investigating the ex-
9 tent to which sponsors of clinical studies of investigational
10 drugs, biologics, and devices and sponsors of applications
11 for approval or licensure of new drugs, biologics, and de-
12 vices comply with Food and Drug Administration require-
13 ments and follow guidance for presentation of clinical
14 study safety and effectiveness data by sex, age, and racial
15 subgroups.

16 (b) REPORT BY GAO.—

17 (1) SUBMISSION.—Not later than 12 months
18 after the date of the enactment of this Act, the
19 Comptroller General shall complete the study under
20 subsection (a) and submit to the Committee on En-
21 ergy and Commerce of the House of Representatives
22 and the Committee on Health, Education, Labor,
23 and Pensions of the Senate a report on the results
24 of such study.

25 (2) CONTENTS.—The report required by para-
26 graph (1) shall include each of the following:

1 (A) A description of the extent to which
2 the Food and Drug Administration assists
3 sponsors in complying with the requirements
4 and following the guidance referred to in sub-
5 section (a).

6 (B) A description of the effectiveness of
7 the Food and Drug Administration's enforce-
8 ment of compliance with such requirements.

9 (C) An analysis of the extent to which fe-
10 males, racial and ethnic minorities, and adults
11 of all ages are adequately represented in Food
12 and Drug Administration-approved clinical
13 studies (at all phases) so that product safety
14 and effectiveness data can be evaluated by gen-
15 der, age, and racial subgroup.

16 (D) An analysis of the extent to which a
17 summary of product safety and effectiveness
18 data disaggregated by sex, age, and racial sub-
19 group is readily available to the public in a
20 timely manner by means of the product label or
21 the Food and Drug Administration's Website.

22 (E) Appropriate recommendations for—

23 (i) modifications to the requirements
24 and guidance referred to in subsection (a);
25 or

1 (ii) oversight by the Food and Drug
2 Administration of such requirements.

3 (c) REPORT BY HHS.—Not later than 6 months
4 after the submission by the Comptroller General of the
5 report required under subsection (b), the Secretary of
6 Health and Human Services shall submit to the Com-
7 mittee on Energy and Commerce of the House of Rep-
8 resentatives and the Committee on Health, Education,
9 Labor, and Pensions of the Senate a response to that re-
10 port, including a corrective action plan as needed to re-
11 spond to the recommendations in that report.

12 (d) DEFINITIONS.—In this section:

13 (1) The term “biologic” has the meaning given
14 to the term “biological product” in section 351(i) of
15 the Public Health Service Act (42 U.S.C. 262(i)).

16 (2) The term “device” has the meaning given to
17 such term in section 201(h) of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 321(h)).

19 (3) The term “drug” has the meaning given to
20 such term in section 201(g) of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 321(g)).

1 **SEC. 3. REPORTING ON QUALITY OF AND ACCESS TO CARE**
2 **FOR WOMEN WITH CARDIOVASCULAR DIS-**
3 **EASES.**

4 Part P of title III of the Public Health Service Act
5 (42 U.S.C. 280g et seq.) is amended by adding at the end
6 the following:

7 **“SEC. 399V-5. REPORTING ON QUALITY OF AND ACCESS TO**
8 **CARE FOR WOMEN WITH CARDIOVASCULAR**
9 **DISEASES.**

10 “Not later than September 30, 2013, and annually
11 thereafter, the Secretary of Health and Human Services
12 shall prepare and submit to the Congress a report on the
13 quality of and access to care for women with heart disease,
14 stroke, and other cardiovascular diseases. The report shall
15 contain recommendations for eliminating disparities in,
16 and improving the treatment of, heart disease, stroke, and
17 other cardiovascular diseases in women.”.

18 **SEC. 4. EXTENSION OF WISEWOMAN PROGRAM.**

19 Section 1509 of the Public Health Service Act (42
20 U.S.C. 300n-4a) is amended—

21 (1) in subsection (a)—

22 (A) by striking the heading and inserting
23 “IN GENERAL.—”; and

24 (B) in the matter preceding paragraph (1),
25 by striking “may make grants” and all that fol-
26 lows through “purpose” and inserting the fol-

Passed the House of Representatives September 30
(legislative day September 29), 2010.

Attest: LORRAINE C. MILLER,
Clerk.